IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. MICHAEL S. LORD, Plaintiffs/Relator, vs. NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, NAPA MANAGEMENT SERVICES CORPORATION, NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, and POCONO MEDICAL CENTER, Defendants.	Civil Action No. 3:13-CV-2940 (JUDGE MANNION) ELECTRONICALLY FILED

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS COUNTS I-II AND IV-VI BY DEFENDANTS NAPA MANAGEMENT SERVICES CORPORATION AND NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC

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INTRODUCTION

Defendants NAPA Management Services Corporation (NAPA-MGMT) and North American Partners in Anesthesia (Pennsylvania), LLC (NAPA-PA) (collectively, NAPA) move to dismiss Counts I-II and IV-VI of Plaintiff Michael Lord's (Lord) Complaint.[1] Lord, a former NAPA-PA employee, alleges that NAPA violated the False Claims Act (FCA) by submitting false claims to Medicare for reimbursement of medically directed anesthesiology services. He also asserts state law claims involving his separation of employment from NAPA-PA. These claims should be dismissed under Fed. R. Civ. P. 12(b)(6) because each fails to state a viable cause of action. The FCA claims should also be dismissed for failure to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b).

BACKGROUND

I. THE PARTIES

NAPA-PA partners with hospitals and other health care facilities, including defendant Pocono Medical Center (PMC), to provide anesthesia services to patients. Complaint at ¶¶ 10-11. NAPA-MGMT provides management services to NAPA-PA. *Id.* at ¶ 9. Lord is a certified registered nurse anesthetist (CRNA) who previously worked for NAPA-PA from June 2011 to June 2013. *Id.* at ¶¶ 6, 10, 51.

[1] Lord has withdrawn his claims against defendant North American Partners in Anesthesia, LLP.

II. RELEVANT MEDICARE FRAMEWORK

Medicare reimburses four categories of anesthesia services: (1) personally performed, (2) medical direction, (3) medical supervision, and (4) not medically directed. 42 C.F.R. §§ 414.46(c), (d), (f), 414.60(a). "Personal performance" occurs when the physician "performs the entire anesthesia service alone." 42 C.F.R. § 414.46(c)(1)(i). Personally performed services are reimbursed at a fee schedule amount set by Medicare. 42 C.F.R. § 414.46(c)(2); Medicare Claims Processing Manual (MCPM), Ch. 12, §§ 50.K.[2]

"Medical direction" generally occurs when an anesthesiologist directs CRNAs in two to four concurrent cases and satisfies the following seven steps:

1. Perform a pre-anesthetic examination and evaluation;
2. Prescribe the anesthesia plan;
3. Personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence;
4. Ensure that any procedures in the anesthesia plan that he does not perform are performed by a qualified individual;
5. Monitor the course of anesthesia administration at frequent intervals;
6. Remain physically present and available for immediate diagnosis and treatment of emergencies; and
7. Provide indicated post-anesthesia care.

[2] Chapter 12 of the MCPM is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf. The Court may consider the MCPM in deciding this motion because it is referenced in ¶ 44 of the Complaint, and is a proper subject for judicial notice. *See Adams v. Luzerne County*, 36 F. Supp.3d 511, 516 (M.D. Pa. 2014). *See also U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp.2d 709, 721 n. 63 (N.D. Tex. 2011) (taking judicial notice of Medicare Program Integrity Manual).

42 C.F.R. § 415.110(a)(1) (the Seven Steps regulation). The physician must document in the patient's medical record that "he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable."[3] 42 C.F.R. § 415.110(b).

"Medical supervision" occurs when the anesthesiologist is involved in medically directing more than four concurrent cases or performs other services while directing concurrent cases. 42 C.F.R. § 414.46(f); MCPM, Ch. 12, § 50.D. Claims for medically supervised services are generally paid at a lower reimbursement rate than if the services were medically directed. 42 C.F.R. § 414.46(f); MCPM, Ch. 12, §§ 50.D, 50.K.

Finally, a CRNA may provide anesthesia services that are "not medically directed" by an anesthesiologist. 42 C.F.R. § 414.60(a). Medicare reimburses the CRNA, or the CRNA's group practice, the same amount an anesthesiologist would receive for personally performing the same service. *Id.*; MCPM, Ch. 12, § 140.3.3.

[3] If the conditions for medical direction are met, the physician is reimbursed 50 percent of the amount allowed for personally performed services and the CRNA, or group practice employing the CRNA, receives the other 50 percent. 42 C.F.R. §§ 414.46(d)(3)(v), 414.60(a), (b). In other words, Medicare reimburses the same amount for personal performance as it does for medical direction, but splits the reimbursement for medical direction between the anesthesiologist and CRNA.

LEGAL STANDARDS

I. FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

Rule 12(b)(6) permits a court to dismiss all or part of an action for "failure to state a claim upon which relief can be granted." To survive a motion to dismiss, a plaintiff's factual allegations "must be enough to raise a right to relief above a speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A complaint must include sufficient facts to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim has "facial plausibility" when it enables the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

II. FEDERAL RULE OF CIVIL PROCEDURE 9(b)

An FCA complaint must also meet the heightened pleading standard of Rule 9(b), which requires the plaintiff to "state with particularity the circumstances constituting the fraud." *See U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 301 n. 9 (3d Cir. 2011); Fed. R. Civ. P. 9(b). To satisfy Rule 9(b), the plaintiff must allege the "who, what, when, where and how of the events at issue." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997). He must allege enough facts for the court "to draw an inference of fraud"; "allegations in the form of conclusions or impermissible speculation . . . are insufficient." *Alvarez v. Ins. Co. of N. Am.*, 313 Fed. Appx. 465, 467-68 (3d Cir. 2008). In an

FCA action, the relator must allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Judd v. Quest Diagnostics Inc.*, 638 Fed. Appx. 162, 168-69 (3d Cir. 2015).

ARGUMENT

I. COUNTS I-II SHOULD BE DISMISSED UNDER RULES 12(b)(6) AND 9(b) FOR FAILURE TO STATE A CLAIM AND PLEAD FRAUD WITH PARTICULARITY

Lord alleges that NAPA violated the FCA by engaging in a "fraudulent billing scheme" in which false claims and records were submitted to Medicare. The crux of Lord's allegations is that NAPA billed Medicare for "medically directed" services that were ineligible for reimbursement at that level because the anesthesiologists failed to satisfy the Seven Steps regulation. Complaint at ¶¶ 2-3. Lord contends that NAPA should have been reimbursed at the lower "medically supervised" rate in those cases. *Id.* at ¶¶ 3, 70.

Counts I and II allege violations of 31 U.S.C. §§ 3729(a)(1) and 3729(a)(2), respectively.[4] To state a claim under these provisions, a relator must show: (1) the defendant presented or caused to be presented to an agent of the United States a

[4] Liability is established under § 3729(a)(1) when a party "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the government; liability under § 3729(a)(2) is shown when a party "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *See U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007).[5] The false claim must also be "material" to the government's decision to pay the claim. *See Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016).

A. COUNTS I AND II SHOULD BE DISMISSED FOR CLAIMS BEFORE JUNE 2011 OR AFTER JUNE 2013

Lord worked for NAPA-PA from June 2011 to June 2013; he filed his Complaint on December 6, 2013. *See* Complaint at 1 and ¶ 6. Lord alleges, on information and belief, that NAPA's purported misconduct occurred since 2007, *id.* at ¶¶ 221, 234, a date presumably based on the FCA's six-year statute of limitations. *See* 31 U.S.C. § 3731(b)(1). Lord's Complaint, however, **does not include a single factual allegation** involving Counts I or II that pertains to NAPA's conduct outside the June 2011 to June 2013 time period.

Rule 9(b) requires Lord to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Quest Diagnostics*, 638 Fed. Appx. at 168-69.

[5] A claim or statement is "false" under the FCA when it is "objectively untrue." *U.S. ex rel. Thomas v. Siemens AG*, 593 Fed. Appx. 139, 143 (3d Cir. 2014). A person acts "knowingly" when he or she has "actual knowledge" of the information or acts in "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1).

Speculation about the existence of fraud is not enough. *See Alvarez*, 313 Fed. Appx. at 467-68. Since Lord has not identified **any** facts that would lead to a "strong inference" that NAPA submitted false claims before June 2011 or after June 2013, Counts I and II should be dismissed as to claims outside those dates. *See U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 Fed. Appx. 693, 709 (11th Cir. 2014) (FCA claims dismissed for time period after employment ended).

B. LORD FAILS TO IDENTIFY VIOLATIONS OF THE SEVEN STEPS REGULATION OR ALLEGE A FALSE CLAIM

A claim is not "false" under the FCA when it is consistent with regulations governing the program in question. *See U.S. ex rel. Glass v. Medtronic, Inc.*, 957 F.2d 605, 608 (8th Cir. 1992). To be actionable, a claim must be "objectively untrue." *Siemens AG*, 593 Fed. Appx. at 143. Lord contends that NAPA submitted false claims to Medicare for medically directed anesthesiology services despite knowing its physicians had failed to satisfy the Seven Steps. In reality, Lord's Complaint describes little more than a series of unrelated practices – many of which do not even involve Medicare – that fail to state violations of the Seven Steps regulation or otherwise identify claims that were objectively untrue.

1. Claims Based on the Immediate Availability Allegations

Lord alleges that NAPA physicians "routinely" provided patient coverage for CRNAs when the CRNAs took morning or lunch breaks, and did so while

medically directing other concurrent cases.[6] Complaint at ¶ 70. Lord contends that it was "impossible" for covering physicians to satisfy the Seven Steps during break periods because they could not leave the patient's side until the CRNA returned and were therefore not immediately available to assist with their other concurrent cases while providing break coverage. *Id.* at ¶¶ 2, 70, 224.

This argument is belied by Lord's own pleading, which acknowledges in ¶ 225 that "immediate availability" may be met by:

> (a) a second anesthesiologist assuming temporary medical direction responsibility for the anesthesiologist providing temporary relief [to the CRNA]; (b) the relieved CRNA remaining in the immediate area so he can return immediately to the procedure; or (c) a specified anesthesiologist remaining available to provide substitute medical direction services for the anesthesiologist providing temporary relief.

In other words, because NAPA-PA is a group practice, multiple physicians and CRNAs are on site at any given time and are available to help satisfy the Seven Steps when a physician provides break coverage for a CRNA. *See* at ¶¶ 75-90, 126-27, 155-56, 163-64. Indeed, CMS guidance recognizes that physicians who are part of a group practice may collaborate in providing medical direction:

[6] As evidence of this "routine" practice, Lord identifies just 13 examples over a one-year period from June 2012 to June 2013. *Id.* at ¶¶ 75-90. Eight of these examples identify when the break purportedly began but do not indicate when it ended, while three others do not provide any information at all about the length of the break. *Id*. at ¶¶ 75, 77-81, 84, 86-87, 89-90. Seven of these examples involved morning breaks, which presumably lasted only about 15 minutes each. *Id*. at ¶¶ 75, 77, 80-81, 86, 89-90.

> If anesthesiologists are in a group practice, one physician member may provide the pre-anesthesia examination and evaluation while another fulfills the other criteria [for medical direction]. Similarly, one physician member of the group may provide post-anesthesia care while another member of the group furnishes the other component parts of the anesthesia service.

MCPM, Ch. 12, § 50.C.

The availability of other NAPA clinicians to assist with medical direction poses an obvious obstacle to Lord's claims. Lord seeks to avoid that issue by making a sweeping fact-devoid assertion that NAPA anesthesiologists "do not arrange for another anesthesiologist to meet the immediate availability criteria for medical direction while the attending anesthesiologist . . . is elsewhere providing CRNA relief." Complaint at ¶ 72. Furthermore, for each of the examples in which a physician supposedly provided break coverage for a CRNA, Lord makes the same naked assertion that the doctor "did not arrange adequate medical direction coverage in his absence." *Id.* at ¶¶ 75-81, 84-87, 89-90. These allegations cannot save Lord's claims. *See Iqbal*, 556 U.S. at 679 (pleadings that are no more than conclusions are not entitled to the assumption of truth).

Lord's allegations assume that a physician must "arrange adequate medical direction" when providing a CRNA with break relief. The Complaint shows, however, that other NAPA physicians and CRNAs were readily available and communicated with one another by phone across different operating rooms to request assistance when needed. *Id.* at ¶¶ 79, 81-85, 88. As Lord acknowledges, if

a physician provides break coverage for a CRNA while medically directing concurrent cases, other doctors remain available to assume medical direction responsibilities if necessary. *Id.* at ¶ 225. Alternatively, the CRNA taking a break can be asked to return to the operating room if the covering physician must assist with another case. *Id.* Lord does not meet his pleading burden of establishing that other members of the NAPA team were unavailable in the examples he provides.

Indeed, Lord does not allege **any** facts to support his conclusory assertion, repeated in rote fashion, that the doctors he references failed to "arrange adequate medical direction coverage in [their] absence." *Id.* at ¶¶ 75-81, 84-87, 89-90. Moreover, even assuming that a physician who provides break relief while medically directing other cases must prospectively arrange for coverage of his or her concurrent cases during that period, Lord does not explain if or how he knows that the doctors in his examples failed to do so. In short, Lord does not meet his Rule 12(b)(6) burden of pleading facts that allow the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 678, nor his Rule 9(b) burden of "injecting precision and some measure of substantiation into [his] allegations of fraud." *Kolar v. Preferred Real Estate Inv., Inc.*, 361 Fed. Appx. 354, 363 n. 8 (3d. Cir. 2010).[7]

[7] At most, Lord's allegations raise a **mere possibility** of noncompliance, which is not enough to survive a motion to dismiss. *See Iqbal*, 556 U.S. at 679.

Lord also claims that on three occasions unrelated to breaks, the physician who was medically directing him was not immediately available to assist with emergence and either extubation or removal of the laryngeal mask airway (LMA). Complaint at ¶¶ 82-83, 88. Lord contends that NAPA failed to satisfy the Seven Steps in these three cases based on his assertions that the physicians were not "immediately available" when he requested their assistance with emergence and "did not arrange for adequate medical direction coverage in [their] absence." *Id.* These allegations fail to show a regulatory violation or otherwise plead a false claim. *See Iqbal*, 556 U.S. at 664 ("mere conclusions" "are not entitled to the assumption of truth"); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (complaint must "show" an entitlement to relief with its facts).[8]

Although the Seven Steps regulation requires physicians to be "available for immediate diagnosis and treatment of emergencies," 42 C.F.R. § 415.110(a)(1)(vi), Lord does not allege that any of the examples he provides presented emergencies that required the physicians' immediate attention. Moreover, Lord's allegations do

[8] Lord does not allege that the physicians were unable to assist him because they were providing break relief for a CRNA. Rather, according to Lord, these doctors were providing him with medical direction, Complaint at ¶¶ 82-83, 88, and presumably were doing the same for other cases. It is entirely permissible for doctors to medically direct up to four concurrent cases and bill for medical direction as long as they satisfy the Seven Steps. Lord's bald assertion that the physicians were not "immediately available throughout the course of the anesthetic" does not show that the doctors failed to meet those requirements.

not show that the physicians failed to participate in "emergence" of a patient from anesthesia, but only that they did not immediately respond to Lord's request for assistance. Complaint at ¶¶ 82-83, 88. These allegations are insufficient because emergence is not a specific, well-defined moment during anesthesia, as Lord suggests, but is an ambiguous term that may include a patient's recovery in the post-anesthesia care unit (PACU). *See U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 878 (8th Cir. 2016).[9] Lord's allegations do not exclude the possibility that the physicians in his examples participated in emergence in the PACU or that they were present for emergence in the operating room outside the time when Lord performed extubation or LMA removal. Finally, Lord's allegations that the physicians in his examples did not assist with extubation or LMA removal do not establish regulatory violations because those procedures are not elements required to be performed by the physician under the Seven Steps regulation. *See* 42 C.F.R. § 415.110(a)(1).

[9] The relator in *Donegan* claimed that the defendant anesthesiology provider violated the FCA by submitting claims for medical direction even though its physicians were "virtually never present with patients during 'emergence[.]'" *Id.* The relator claimed that emergence ends when the patient leaves the operating room and is delivered to the PACU, while the defendant argued that emergence includes the patient's recovery in the PACU. *Id.* at 878-79. After considering the opinions of the parties' experts, including one who opined that "emergence from general anesthesia is a process and has no discrete point in time," the court concluded that the defendant's interpretation was "objectively reasonable" and that this reasonable interpretation of ambiguous regulatory guidance precluded a finding that the defendant had knowingly submitted false claims. *Id.*

2. Claims Based on the Attestation Allegations

Lord alleges that physicians pre-signed attestations in patient medical records that stated, "I was present for induction, key portions of the procedure and emergence; and immediately available throughout." *Id.* at ¶ 91. Lord contends that in doing so, the physicians violated Medicare rules because they "**may not** [have] actually [met] the [Seven Step] requirements attested to during the course of the patient's anesthetic." *Id.* at ¶ 95 (emphasis added). These speculative allegations do not meet the heightened pleading requirements of Rule 9(b) or describe a Seven Steps violation. *See Twombly*, 550 U.S. at 555 (to survive a motion to dismiss, factual allegations "must be enough to raise a right to relief above a speculative level").

To satisfy Rule 9(b), a plaintiff must allege the "who, what, when, where and how of the events at issue." *In re Burlington Coat Factory*, 114 F.3d at 1422. Although Lord provides 25 examples of alleged pre-signed attestations, 21 of them fail to identify the patient's name and 22 fail to allege (a) that the patient was a Medicare patient, (b) that NAPA submitted claims for Medicare reimbursement, or (c) that any claims were for medically directed services. *Id.* at ¶¶ 98-118, 120-22. These allegations do not support a "strong inference" that false claims – or even any claims – were submitted to Medicare, as required under 9(b). *See Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157-58 (3d Cir. 2014).

The Seven Steps regulation requires anesthesiologists to document in the patient's medical record "that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable." 42 C.F.R. § 415.110(b). The regulation, however, does not address how this documentation is to occur or in what format. Although pre-signing an attestation (even if true) may not be a "best practice," Lord fails to show why doing so is fraudulent or even non-compliant with the Seven Steps regulation. For example, Lord does not allege facts showing that the physicians subsequently failed to perform the services listed in the purportedly pre-signed attestations.

Finally, the attestation allegations fail to show the submission of any false claims. To establish an FCA claim, a relator must show that the defendant knowingly submitted a materially false claim to the government. *See U.S. ex rel. Thomas v. Siemens AG*, 991 F. Supp.2d 540, 567 (E.D. Pa. 2014). To survive a motion to dismiss, a relator must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 157-58. The attestation-related allegations, which do not allege the submission of any Medicare claims, fail to meet this standard. *See* Complaint at ¶¶ 98-118, 120-22.

3. Claims Based on the Examination Allegations

Lord contends that NAPA physicians failed to perform complete pre-anesthetic examinations and evaluations for some patients. *Id.* at ¶¶ 123-44. He offers 15 examples of "incomplete and substandard" examinations, two of which do not involve Medicare patients. *Id.* at ¶¶ 125-41. Lord also alleges that doctors failed to conduct physical exams of six patients, but falsely documented in the patients' medical records that the examinations were performed. *Id.* at ¶¶ 145-54. Only one of these patients was a Medicare patient. Id. at ¶ 146.

To satisfy the Seven Steps, a physician must "[p]erform[] a pre-anesthetic examination and evaluation." 42 C.F.R. § 415.110(a)(1)(i). Except for the one Medicare patient that Lord claims did not receive a physical exam, Complaint at ¶ 146,[10] he does not allege that NAPA's physicians failed to conduct the evaluations in their entirety. Rather, he bases his claims on his **personal opinion** that certain assessments were "incomplete and substandard." *Id.* at ¶¶ 125-41. Lord identifies just 13 Medicare patients from his two-year tenure at NAPA and cherry picks items from their evaluations that he contends were not adequately addressed.[11] *Id.*

[10] Lord apparently concedes that the doctor completed other aspects of the evaluation. *Id.* at ¶145-46.

[11] These allegations would be better suited to a medical malpractice action than an FCA case. *See Escobar*, 136 S. Ct. at 2004 (FCA is concerned with "allegations of fraud, not medical malpractice").

Although the Seven Steps regulation requires physicians to perform pre-anesthetic examinations and evaluations, it does not provide any guidance on what these assessments must include as a condition of payment from Medicare. Indeed, while Lord goes to great lengths to allege deficiencies in the patients' Evaluation Forms, such as noting items that the physician did not check off, the only information the Seven Steps regulation requires an anesthesiologist to document in the patient's medical record is the fact that "he or she performed the pre-anesthetic exam and evaluation." 42 C.F.R. § 415.110(b). Moreover, Lord does not allege any facts showing that the Evaluation Form used by NAPA physicians, or the discrete categories of information contained within it, is a Medicare mandated document that must be fully completed in order to receive reimbursement.

How a physician performs a patient examination or evaluation is within his or her own clinical judgment. Lord's **opinion** that 13 assessments were "incomplete and substandard" does not, by itself, give rise to a false claim. Rather, to be actionable, a claim must constitute an "objective falsehood." *See Siemens AG*, 593 Fed. Appx. at 143. At most, Lord's allegations describe a difference of opinion between him and the doctors with whom he worked about how to conduct and document an examination. But claims are not "false" when reasonable people can disagree about whether a service is properly billed to the government. *See U.S. ex rel. Hill v. Univ. of Med & Dentistry*, 448 Fed. Appx. 314, 316 (3d Cir. 2011);

United States v. AseraCare Inc., 176 F. Supp.3d 1282, 1283 (N.D. Ala. 2016) ("A mere difference of opinion between physicians, *without more*, is not enough to show falsity"); *U.S. v. Prabhu*, 442 F. Supp.2d 1008, 1026 (D. Nev. 2006)

Finally, Lord claims that a physician falsified an Evaluation Form for a single Medicare patient by indicating that he had performed an examination of the patient when, according to Lord, he had not actually done so. Complaint at ¶ 146. Lord does not explain how he knows the doctor failed to examine the patient and does not provide any details that would enable the Court to draw a "strong inference" of fraud, such as facts that might exclude the possibility that the doctor examined the patient outside of Lord's presence. *See Quest Diagnostics Inc.*, 638 Fed. Appx. at 168-69. Lord's bare allegation that the doctor failed to examine the patient is not entitled to the assumption of truth. *See Iqbal*, 556 U.S. at 679; *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 224 (3d Cir. 2011).

4. Claim Based on the Informed Consent Allegation

Finally, Lord alleges that NAPA submitted a false claim to Medicare in May 2012, after doctors failed to obtain adequate informed consent from a dementia patient before anesthesia. *Id.* at ¶¶ 155-160. Obtaining informed consent, however, is not a required element of the Seven Steps regulation. *See* 42 C.F.R. § 415.110(a)(1). Moreover, these allegations reflect, at most, a difference of opinion between Lord and the anesthesiologists involved about what constitutes informed

consent under the circumstances. Expressions of opinion or conclusions about which reasonable minds may differ are not false under the FCA. *See Hill*, 448 Fed. Appx. at 316; *AseraCare*, 176 F. Supp.3d at 1283.

C. NAPA'S ALLEGED VIOLATIONS OF THE SEVEN STEPS REGULATION ARE NOT MATERIAL

To be actionable, NAPA's alleged violations of the Seven Steps regulation must be material to Medicare's payment decision. *See Escobar*, 136 S. Ct. at 2002. The materiality requirement is "demanding," as the FCA is not a "vehicle for punishing garden-variety . . . regulatory violations." *Id.* at 2003. Materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* "Nor is it sufficient . . . that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* "[T]he fundamental inquiry is 'whether a piece of information is sufficiently important to influence the behavior of the recipient.'" *United States ex rel. Escobar v. Universal Health Serv., Inc.*, 842 F.3d 103, 110 (1st Cir. 2016) (citation omitted).

Materiality must be pled with particularity. *See Escobar*, 136 S. Ct. at 2004 n. 6. However, the only arguable materiality allegations in the Complaint are Lord's bald assertions that the government authorized payment to NAPA in reliance on the company's alleged false claims. Complaint at ¶¶ 231-32, 235, 237. These allegations are insufficient. Lord has failed to allege any facts that would meet the "demanding" materiality standard. He has not shown that NAPA

misrepresented matters "so central" that Medicare "would not have paid [NAPA's] claims had it known of these violations." *Escobar*, 136 S. Ct. at 2004.

Lord's claims are based on a series of unrelated practices, many of which do not even involve Medicare, and which, at most, involve minor cases of noncompliance.[12] Even if Lord's allegations are true, he fails to show that Medicare would have declined payment for the violations he alleges. Indeed, even if NAPA's alleged noncompliance would have entitled Medicare to decline payment, this is not enough for materiality. *See Escobar*, 136 S. Ct. at 2003 (rejecting view "that any . . . regulatory . . . violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation"). Lord's failure to show that Medicare would have declined payment under the circumstances is fatal to his FCA claims.

Finally, Lord's allegations fail to show that Medicare would have paid NAPA at the lower "medically supervised" rate had NAPA failed to satisfy the Seven Steps. In fact, at least one Medicare Administrative Contractor (MAC) maintained guidance in 2013, stating that if an anesthesiologist medically directed CRNAs in up to four concurrent cases but was not immediately available for some portion of a case because of an intervening factor, the CRNA's services "should be

[12] Claims that do not involve Medicare obviously cannot be material since the FCA would not apply in the absence of a request for payment from the government.

billed as non-medically directed or 'QZ.'" Declaration of David M. Vaughn (Vaughn Dec.) (attached as **Exhibit 1**) at Exhibit E, FAQ 5.[13] In that case, the "not medically directed" category (billed under modifier QZ) would have paid a group practice like NAPA the same amount as "medical direction." *See* 42 C.F.R. §§ 414.46(c)(2), 414.46(d)(3)(v), 414.60(a), 414.60(b); MCPM, Ch. 12, §§ 50.K and 140.3.3. Since the reimbursement would have been the same in either case, it is unlikely that knowledge of NAPA's alleged failure to meet the Seven Steps for medical direction would have influenced Medicare's payment decision. *See Escobar*, 136 S. Ct. at 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, . . . that is strong evidence that the requirements are not material").

II. COUNT IV SHOULD BE DISMISSED BECAUSE THE PENNSYLVANIA WHISTLEBLOWER LAW DOES NOT APPLY[14]

The Pennsylvania Whistleblower Law ("PWL") prohibits retaliation against an employee who reports "to the employer or appropriate authority . . . an instance

[13] MACs are private entities contracted to assist CMS in administering Medicare. 42 U.S.C. § 1395kk-1(a)(3). MACs may issue Local Coverage Determinations (LCD) describing when items or services may be covered by Medicare on a MAC-wide basis, and may convey information to health care providers through articles, bulletins and FAQs posted on their websites. 42 U.S.C. § 1395ff(f)(2)(B); Vaughn Dec. at ¶ 4. The Court may take judicial notice of LCDs issued by MACs, *see U.S. ex rel. Modglin v. DJO Global Inc.*, 114 F. Supp.3d 993, 1001 n. 36 (C.D. Cal. 2015), and should do the same with respect to this FAQ guidance.

[14] Lord lumps NAPA-PA and NAPA-MGMT together as "NAPA" in these counts, but he was employed only by NAPA-PA. Complaint at ¶¶ 51, 55.

of wrongdoing or waste by a public body or an instance of waste by any other employer." 43 P.S. § 1423(a). Lord alleges that NAPA retaliated against him for reporting "wrongdoing" within the organization. Complaint at ¶¶ 249-53. He must therefore show that NAPA is a "public body" to state a viable PWL claim.

A "public body" includes government officers, political authorities, and other bodies "funded in any amount by or through Commonwealth or political subdivision authority." 43 P.S. § 1422. Lord claims that NAPA is a public body because it receives Medicare and Medicaid payments.[15] Complaint at ¶ 247. However, this Court has rejected similar arguments on more than one occasion.

For instance, in *Zorek v. CVS Caremark Corp.*, No. 1:13-cv-1949, 2014 WL 12487695, *5-7 (M.D. Pa. Apr. 16, 2014) (attached as **Exhibit 2**), the Court dismissed a pharmacist's PWL claim against his former employer, a pharmacy, after rejecting the pharmacist's argument that the organization was a "public body" because it received Medicaid reimbursements. The Court held that "monies remitted to provider participants in reimbursement for Medicaid services rendered do not qualify as 'funding' within the meaning of the PWL." *Id.* at *7. *See also Lampenfeld v. Pyramid Healthcare, Inc.*, No. 3:14-cv-0283, 2015 WL 926154, *9 (M.D. Pa. Mar. 4, 2015) (attached as **Exhibit 3**) (dismissing PWL claim because Medicaid reimbursements do not constitute "funding . . . by or through the

[15] Only NAPA-PA receives government payments for providing patient care.

Commonwealth"); *Cohen v. Salick Health Care, Inc.*, 772 F. Supp. 1521, 1527 (E.D. Pa. 1991) (PWL was "not intended to make an individual or corporation a 'public body' solely on the basis that monies were received by it from the state as reimbursement for services rendered"). Since NAPA is not a "public body" under the PWL, the Court should dismiss Count IV.

III. COUNT V SHOULD BE DISMISSED BECAUSE THE PENNSYLVANIA WAGE PAYMENT AND COLLECTION LAW DOES NOT APPLY TO FUTURE WAGES

The Pennsylvania Wage Payment and Collection Law ("WPCL"), 43 P.S. § 260.1, *et seq.*, is intended "to provide employees a means of enforcing payment of wages and compensation **withheld** by an employer." *Voracek v. Crown Castle USA Inc.*, 907 A.2d 1105, 1109 (Pa. Super. 2006) (emphasis added). Lord does not allege that NAPA wrongfully withheld wages earned during the course of his employment. Instead, he seeks to recover the "compensation and benefits [he] **would have earned** if his employment with NAPA had not ended prematurely." Complaint at ¶ 257 (emphasis added). Since the WPCL does not apply to Lord's claim for future wages, Count V should be dismissed. *See Scully v. US WATS, Inc.*, 238 F.3d 497, 516 (3d Cir. 2001) ("We agree . . . that the WPCL does not give rise to claims for unearned compensation"); *Mikhail v. Aeroseal, LLC*, No. 15-1505, 2016 WL 2346747, *1 (E.D. Pa. May 4, 2016) (attached as **Exhibit 4**); *Allende v. Winter Fruit Distrib., Inc.*, 709 F. Supp. 597, 599 (E.D. Pa. 1989).

IV. COUNT VI, LORD'S WRONGFUL TERMINATION CLAIM, SHOULD BE DISMISSED BECAUSE LORD HAS AN EXISTING STATUTORY REMEDY UNDER THE FCA AND HIS SEPARATION DID NOT VIOLATE PUBLIC POLICY

A. Lord's Wrongful Termination Claim is Preempted by His Existing Statutory Remedies

In Pennsylvania, common law claims for wrongful termination are available only if "there is no statutory remedy for the alleged retaliatory discharge." *U.S. ex rel. Budike v. PECO Energy*, 897 F. Supp.2d 300, 326 (E.D. Pa. 2012). *See also Preobrazhenskaya v. Mercy Hall Infirmary*, 71 Fed. Appx. 936, 941 (3d Cir. 2003) ("Pennsylvania law does not recognize a common law action for violating public policy when there is a statutory remedy"); *McAlee v. Independence Blue Cross*, 798 F. Supp.2d 601, 604, 607 (E.D. Pa. 2011). In Count III, Lord asserts a federal claim under the anti-retaliation provisions of the FCA, 31 U.S.C. § 3730(h). Where, as here, the FCA retaliation claim and wrongful termination claim are based on the same facts, the wrongful termination claim is preempted. *See Budike*, 897 F. Supp.2d at 327. Count VI should therefore be dismissed.

B. Lord's Separation Did Not Violate Public Policy

Under Pennsylvania's employment-at-will doctrine, an employer may terminate an employee for any reason, unless prevented by contract. *See Hicks v. Arthur*, 843 F. Supp. 949, 956-57 (E.D. Pa. 1994). Under a narrow exception to this rule, an employee may bring a wrongful discharge action if the termination

violated a "significant, clearly mandated public policy." *Id.* at 957. Courts have narrowly construed this public policy exception and recognize just three limited situations in which public policy may trump employment at-will. *See Fraser v. Nationwide Ins. Co.*, 352 F.3d 107, 111 (3d Cir. 2003). An employer cannot (1) require an employee to commit a crime and fire the employee for refusing to do so, (2) prevent an employee from complying with a statutorily imposed duty, or (3) discharge an employee when specifically prohibited from doing so by statute. *Id.* *See also Hennessy v. Santiago*, 708 A.2d 1269, 1273 (Pa. Super. 1998) (same).

Lord's wrongful discharge claim does not fit within any of these categories. Lord merely realleges in Count VI that his discharge violated the FCA's retaliation provision (as alleged in Count III), the PWL (as alleged in Count IV), and Pennsylvania's common law against wrongful termination (as alleged in Count VI itself). Complaint at ¶ 263. He also asserts that his discharge violated 18 Pa. C.S.A. § 4953, a criminal law that makes it a felony to harm or threaten anyone in retaliation for anything "done in the capacity of witness, victim or a party in a civil matter." *Id.* That statute, however, does not apply to this case because Lord does not allege that he was a party to any civil matter during the relevant period, nor that

he was a "witness" or "victim" in any criminal matter.[16] Thus, Lord's wrongful discharge claim should be dismissed.

CONCLUSION

For the foregoing reasons, the Court should dismiss Counts I-II and IV-VI with prejudice.

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[16] A "victim" is a person against whom a crime "is being or has been perpetrated or attempted", while a "witness" is a person with knowledge "relating to any crime." 18 Pa. C.S.A. § 4951.

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. MICHAEL S. LORD, Plaintiffs/Relator, vs. NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, NAPA MANAGEMENT SERVICES CORPORATION, NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, and POCONO MEDICAL CENTER, Defendants.	Civil Action No. 3:13-CV-2940 (JUDGE MANNION) ELECTRONICALLY FILED

CERTIFICATE OF SERVICE

BRIAN K. FRENCH, ESQUIRE, hereby certifies that, on the 22nd day of March, 2017, he caused to be served a true and correct copy of the foregoing Declaration of David M. Vaughn in Support of Motion to Dismiss, by ECF, to all counsel of record.

NIXON PEABODY, LLP

By: /S/ Brian K. French, Esquire
Brian K. French, Esquire